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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

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COVID-19 In Vitro Diagnostic Medical Device - detail

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Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

Manufactured by Guangzhou Wondfo Biotech Co.,
Ltd, China - en.wondfo.com.cn/ 

Device
identification
number
1437

CE Marking ✓ Yes

HSC	✓ Yes
common list	
HSC mutual recognition	✓ Yes
Format	Near POC / POC
Physical Support	Cassette, Lateral flow
Target	Antigen
Specimen	Other
Commercial Status	Commercialised
Last Update	2021-05-10 08:07:30 CET

[Show HSC list status history](#) ✓

Assay Type	Immuno-Antigen
Rapid Diagnostic	Yes
Reader Required	No
Method	Immunoassay
Measurement Qualitative	
Time	15 minutes

Detection Principle	Fluorescence
LOD	850 AU
Calibration	evaluated
Crossreactivity	evaluated
Precision	evaluated
Accuracy	see IFU
Reproducibility	evaluated
Robustness	evaluated
Clinical Sensitivity	see IFU

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.

[Acknowledgements](#)

COVID-19 Test Methods and Devices

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